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Janssen-Cilag

8 October 2010

Dear [redacted]

Final Appraisal Determination: bortezomib and thalidomide for the first-line treatment of multiple myeloma

Thank you for your response to the initial scrutiny of your appeal lodged against this FAD. This letter represents the final decision on initial scrutiny.

1.3 In deciding to place less weight on thalidomide studies which included a maintenance phase, the appraisal committee relied on evidence from the assessment group which has not been disclosed to consultees

It remains my view that there cannot be unfairness in your not being allowed to comment on a response to your own comments. Your right is to be consulted fairly. A fair consultation requires that you are given sufficient material to make an intelligent response, and that your response is taken into account. If your consultation response is for some reason found unpersuasive, there is no right to make further comment on the reasons for that.

However, I am going to refer this point to the appeal panel, but strictly on the basis that the issue is the fairness of the consultation exercise carried out on the ACD.

Further, I note that the assessment group did model the effect of including the thalidomide studies with a maintenance phase, and these are referenced in the FAD at 4.2.22. There is no need to speculate what the effect might have been had you persuaded the committee to take them into account. Against that background, if the appeal panel were to find you had been treated unfairly, it seems to me that the issue of whether that unfairness could have made any difference to the outcome is a live one. I would expect the appeal panel to wish to explore this and suggest you may wish to make a representation on it.

1.4 While the appraisal committee decided that the thalidomide studies which included a "maintenance" phase should receive less weight than those with no maintenance phase, such

weighting is unexplained and appears inconsistent with NICE's Guide to the methods of technology appraisal

Although I have considered your additional argument with care, it remains my view that you are merely disagreeing with the weight given to these studies. I do not see that the passage cited from the Methods Guide requires any exceptional level of reasoning in the FAD or supporting documents.

My decision is that this is not a valid ground of appeal.

2.3 The Appraisal Committee's conclusion at paragraph 4.3.8 of the FAD that an assessment of cost effectiveness which assumes use of 31.5 vials of bortezomib "should be considered the most optimistic estimate for clinical practice" is inconsistent with the available evidence.

Although I have considered your additional argument with care, it remains my view that this point is invalid. To my mind, the issue is whether the use of fewer than 31.5 vials has any real-world plausibility, such that it would be unreasonable not to have modelled it. (Vial sharing is a separate issue which will be considered under appeal point 2.4) Without that plausibility there can be no objection to it not having been considered.

You have advanced no evidence based grounds for supposing that use of fewer than 31.5 vials is plausible. You yourselves modelled a mean of 31.5 vials, and I cannot see any basis in your letters or the appraisals documentation for supposing that fewer than 31.5 vials would be an informative scenario to have modelled.

I also have severe reservations about whether it could be legitimate to model use of fewer vials without also revisiting clinical effectiveness, an issue your appeal point does not consider. Prima facie, if the argument is that each patient may receive less drug, it would seem necessary to ask whether the patient does not also receive less benefit.

I note and accept that you take issue with the description of 31.5 as "most optimistic". Clearly there is a difference of opinion, but I cannot see that it could arguably amount to unreasonableness. Even if 31.5 was not optimistic but actual, that would not of itself justify or require modelling lesser use, unless there was some reason to suppose lesser use might occur. Provided a usage of 31.5 vials has been modelled and considered, as it has been, and in the absence of any substantive argument as to why a lesser number would be credible, I cannot see a valid appeal on the grounds of reasonableness here.

Conclusion

This is the final decision on initial scrutiny. The valid appeal points are.1.1, 1.2, 1.3, 2.1, 2.2, and 2.4.

Yours sincerely

Maggie Helliwell

Appeals Committee Chair

National Institute for Health and Clinical Excellence